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EXAMINER SZNAIDMAN, MARCOS L				
ART UNIT 1628		PAPER NUMBER		
NOTIFICATION DATE 04/01/2011		DELIVERY MODE ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/537,117

Applicant(s)

AWAKURA ET AL.

Examiner

MARCOS L. SZNAIDMAN

Art Unit

1628

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 February 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-20, 23 and 28-39 is/are pending in the application.
- 4a) Of the above claim(s) 14 and 19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-13, 15-18, 20, 23 and 28-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-946)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

This office action is in response to applicant's reply filed on February 2, 2011.

Status of Claims

Amendment of claims 11, 16, and 29-31, cancellation of claims 21-22 and 24-27, and addition of claims 36-39 is acknowledged.

Claims 11-20, 23, 28-39 are currently pending and are the subject of this office action.

Claims 14 and 19 were withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on January 16, 2009.

Claims 11-13, 15-18, 20, 23 and 28-39 are presently under examination.

The following species, elected by Applicant in the reply filed on January 16, 2009, are under examination: potassium phosphite as the elected species for Compound A.

Priority

The present application is a 371 of PCT/JP03/15543 filed on 12/04/2003, and claims priority to foreign application: JAPAN 2002-352697 filed on 12/04/2002.

Rejections and/or Objections and Response to Arguments

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated (Maintained Rejections and/or Objections) or newly applied (New Rejections and/or Objections, Necessitated by Amendment or New Rejections and/or Objections not Necessitated by Amendment). They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 103 (New Rejection not Necessitated by Amendment)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

According to MPEP 2111.03:

The transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s) of the claimed invention. *In re Herz*, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976) (emphasis in original).

For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising."

If an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change

the characteristics of applicant's invention. *In re De Lajarte*, 337 F.2d 870, 143 USPQ 256 (CCPA 1964).

In the instant case, Applicant did not provide a clear description of which components would materially change the characteristics of the invention. The specification (see page 6, lines 5-20), even though defines a group of compounds like phosphorous compounds (Compound A) and one or more fungicidal active components (Compound B) does not provide a clear description of which components do materially affect the basic and novel characteristics of the claimed composition.

In summary, as stated above "consisting essentially of" will be construed as equivalent to "comprising."

Claims 11-13, 15-18, 20, 23 and 28-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pirgozliev et. al. (European Journal of Plant Pathology (2002) 108:469-478, cited in prior office action) in view of: Staub et. al. (US 4,849,219, cited in prior office action), Davis et. al. (Plant Pathology (1994) 43:200-205), Gorog nee Privitzer et. al. (US 4,661,477) and Csutak et. al. (US 4,866,043).

Claims 11-13, 15, 29-34 and 36-39 recite a method for reducing mycotoxin contamination (wherein the mycotoxin is deoxynivalenol (DON), see claims 30 and 32) in a cereal (wherein the cereal is wheat, see claims 29 and 33-34) comprising (see above discussion) a step of applying potassium phosphite (species elected) to a seed or

plant of a cereal, in an amount sufficient for inhibiting mycotoxin (DON) production from plant pathogenic fungi in a cereal.

For claims 11-13, 15, 29-34 and 36-39, Pirgozliev teaches a method of inhibiting or reducing the amount of the mycotoxin deoxynivalenol (DON) in wheat comprising the administration of a fungicide like metconazole or azoxystrobin (see for example title and abstract) to the ears of the plant (see for example page 471 under Fungicide application). Pirgozliev further teaches different amounts of fungicide to be applied (see Table 2 on page 471) at a rate of 200 l ha⁻¹. Pirgozliev clearly teaches that *Fusarium* is a destructive fungal disease of wheat and other small grain cereals. Then Pirgozliev teaches the strains that are most associated with the disease (see Introduction, left column). Then Pirgozliev further teaches that DON is one of the mycotoxins produced by several *Fusarium* species (see page 469, right column, second paragraph).

Pirgozliev does not teach reducing DON with potassium phosphite (species elected). However, Staub teaches a fungicidal composition comprising potassium phosphite (e.g. monopotassium phosphite and dipotassium phosphite, see column 4, lines 1 and 3) useful for the treatment of *Fusarium* fungi (see column 5, line 6) in crops like wheat (see column 5, line 24).

The specific combination of features claimed is disclosed within the broad generic ranges taught by the reference but such "picking and choosing" within several variables does not necessarily give rise to anticipation. *Corning Glass Works v. Sumitomo Elec.*, 868 F.2d 1251, 1262 (Fed. Circ. 1989). Where, as here, the reference does not provide any motivation to select this specific combination of variables

(potassium phosphate as the antifungal, *Fusarium* as the fungi, and wheat as the cereal), anticipation cannot be found.

That being said, however, it must be remembered that "[w]hen a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious". *KSR v. Teleflex*, 127 S.Ct. 1727, 1740 (2007)(quoting *Sakraida v. A.G. Pro*, 425 U.S. 273, 282 (1976)). "[W]hen the question is whether a patent claiming the combination of elements of prior art is obvious", the relevant question is "whether the improvement is more than the predictable use of prior art elements according to their established functions." (*Id.*). Addressing the issue of obviousness, the Supreme Court noted that the analysis under 35 USC 103 "need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." *KSR v. Teleflex*, 127 S.Ct. 1727, 1741 (2007). The Court emphasized that "[a] person of ordinary skill is... a person of ordinary creativity, not an automaton." *Id.* at 1742.

Consistent with this reasoning, it would have obvious to have selected various combinations of various disclosed ingredients (potassium phosphate as the antifungal, *Fusarium* as the fungi and wheat as the cereal) from within a prior art disclosure, to arrive compositions "yielding no more than one would expect from such an arrangement".

Staub further teaches that advantageous rates of application are normally from 100 g to 2,000 g a.i./ha (see column 6, lines 13-15). Staub further teaches that the fungicides can be applied to the seeds of the plants (see column 5, line 10).

Davis further teaches that Phosphonates are in general effective in treating a variety of fungi including *Fusarium oxysporum* and *Fusarium avenaceum* (see abstract).

Gorog nee Privitzer teaches that ammonium salts of phosphorous acid esters are effective in treating *Fusarium oxysporum* (see for example Table III, column 18).

Finally, Csutak teaches that 3-isononyloxypropyl-ammonium methyl phosphonate (an ammonium salts of phosphorous acid ester) is effective in treating *Fusarium* diseases (*Fusariosis*) when applied to the seeds of plants and cereals by applying this compound to the seeds (see column 1, lines 27-42 and example 16 on column 7).

Since Pirgozilev teaches reducing DON contamination comprising the administration of a fungicide that controls certain *Fusarium* species and since Straub, Davis, Gorog nee Privitzer and Csutak, all teach that that compositions comprising or consisting of potassium phosphate salts or esters are known fungicides that control certain *Fusarium* species, at the time of the invention it would have been *prima facie* obvious for a person of ordinary skill in the art to substitute one functional equivalence (a fungicide that controls certain *Fusarium* species) for another (potassium phosphate or a related ester) and thus reduce DON contamination resulting from *Fusarium*, with an expectation of success, since the prior art establishes that both function in similar manner, thus resulting in the practice of claims 11-13, 15, 29-34 and 36-39 with a reasonable expectation of success.

Claim 35 further limits claim 11 wherein the amount of deoxynivalenol is reduced to 1.1 ppm or less.

For claim 35, Pirgozliev further teaches: that the FDA recommends that DON concentrations should not exceed 1000 micrograms/kg (i.e. 1 ppm) in finished wheat products (see page 470, left column, middle of the page). Pirgozliev also teaches that depending on the amount and type of fungicide the amount of DON can be reduced to undetectable amounts (less than 1.1 ppm, see Table 5, second and third line of experiment 1).

Based on this, and since it is within the capability of the ordinary skilled in the art to modify amounts for a specific treatment and adjust those particular amounts to observed effectiveness, the skilled artisan would have been further motivated to determine the amount of potassium phosphite required in order to reduce the amount of DON below the level required by the FDA, thus resulting in the practice of claim 35 with a reasonable expectation of success.

Claims 16-18, 20, 23 and 28 further limit claim 11, wherein the composition further comprises an effective amount of at least one fungicidal active ingredient for agri-horticulture (azoxystrobin in claims 23 and 28).

For claims 16-18, 20, 23 and 28 Pirgozliev further teaches a method for reducing the amount of the mycotoxin deoxynivalenol (DON) that is released by *Fusarium*, comprising the administration of azoxystrobin (see abstract).

At the time of the invention it would have been *prima facie* obvious for a person of ordinary skill in the art to inhibit or decrease the amount of deoxynivalenol contamination in wheat, combining two compositions (potassium phosphite and azoxystrobin) each of which is taught by the prior art to be useful for the same purpose (reduce the amount of DON released by *Fusarium*), in order to form a third composition to be used for the very same purpose. The idea of combining them flows logically from their having been individually taught in the prior art (see MPEP 2144.06). *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). All this would result in the practice of claims 16-18, 20, 23 and 28 with a reasonable expectation of success.

Response to Applicant's arguments related to the above rejection

Applicant's arguments have been fully considered but are not persuasive.

Applicant argues that:

Applicant basically repeats the same arguments as in previous responses.

The present inventors were the first to discover that the compounds recited in Applicant's claims have the effect of reducing an amount of a mycotoxin, such as DON, produced in a cereal, independently on controlling of the pathogenic fungi *Fusarium*.

Examiner's response:

As discussed previously (see for example response on pages 6-7 of the office action mailed on 09/15/2009) Applicant was able to show that by increasing the amount

of potassium phosphite administered, both: the mycotoxin DON and the fungi *Fusarium* will decrease, although at a different pace. Initially the amount of DON is decreased without affecting the amount of *Fusarium*, but at higher concentrations, the amount of *Fusarium* also starts to decrease (see Table 6 of the specification). There is nothing unexpected with the above result or discovery.

Since Pirgozliev teaches: that the FDA recommends that DON concentrations should not exceed 1000 micrograms/kg (i.e. 1 ppm) in finished wheat products (see page 470, left column, middle of the page), the skilled in the art will be motivated to reduce the amount of DON below 1.1 ppm, regardless of the amount of *Fusarium* present.

Conclusion

No claims are allowed.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARCOS SZNAIDMAN whose telephone number is (571)270-3498. The examiner can normally be reached on Monday through Thursday 8 AM to 6 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brandon Fetterolf can be reached on 571 272-2919. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MARCOS L SZNAIDMAN/
Primary Examiner, Art Unit 1628
March 25, 2011.